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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,182	06/20/2003	Fritz H. Bach	13681-012001	8996
26161 7590 07/02/2007 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER SAUCIER, SANDRA E	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 07/02/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/600,182

**Applicant(s)**

BACH ET AL.

**Examiner**

Sandra Saucier

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 16-20 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

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***Election/Restrictions***

The indication of allowability of claims 16-20 in the action mailed 1/11/07 is rescinded. Upon further consideration a further, following restriction/election is required. It is noted that applicants' elected Group 33, claims 16-20, in the response filed 1/24/06. A further election/restriction within Group 33 follows.

Group I, claim 16, drawn to a method of transplanting an organ, a tissue, or cells comprising:

administering to the donor a composition comprising:

- (i) NO and
- (ii) another treatment selected from the group consisting of:
  - inducing HO-1 in the donor,
  - expressing HO-1 in the donor,
  - inducing apoferritin in the donor,
  - expressing apoferritin in the donor,
  - administering HO-1 to the donor,
  - administering CO to the donor,
  - administering bilirubin to the donor
  - administering biliverdin to the donor
  - administering ferritin to the donor,
  - administering iron to the donor,
  - administering desferoxamine to the donor,
  - administering salicylaldehyde isonicotinoyl hydrazone to the donor,
  - administering iron dextran to the donor,
  - administering apoferritin to the donor, classified in class 424/93.7, 93,71, 93,73; 514/579, 663, 740; 600/36 and others depending, for example, on the treatment species of (ii).

Group II, claim 17, drawn to a method of transplanting an organ, a tissue or cells comprising:

administering *ex vivo* to the organ, tissue or cells,

- (i) NO and
- (ii) another treatment selected from the group consisting of:
  - inducing HO-1 in the organ, tissue or cells,
  - expressing HO-1 in the organ, tissue or cells,
  - inducing ferritin in the organ, tissue or cells,
  - expressing ferritin in the organ, tissue or cells,
  - administering HO-1 to the organ, tissue or cells,
  - administering CO to the organ, tissue or cells,

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administering bilirubin to the organ, tissue or cells,  
administering biliverdin to the organ, tissue or cells,  
administering ferritin to the organ, tissue or cells,  
administering iron to the organ, tissue or cells,  
administering desferoxamine to the organ, tissue or cells,  
administering salicylaldehyde isonicotinoyl hydrazone to the organ,  
tissue or cells,  
administering iron dextran to the organ, tissue or cells,  
administering apoferritin to the organ, tissue or cells, classified in class  
435/1.1, 1.2, 2; 424/93.7, 93.71, 93.73 and others depending, for example,  
on the treatment species of (ii).

Group III, claims 18-20, drawn to a method of transplanting an organ,  
tissue or cells from a donor into a recipient comprising:

before, during or after transplanting the organ tissue or cells,  
administering to the recipient a composition comprising:

- (i) NO and
- (ii) another treatment selected from the group consisting of:  
inducing HO-1 in the recipient,  
expressing HO-1 in the recipient,  
inducing apoferritin in the recipient,  
expressing apoferritin in the recipient,  
administering HO-1 to the recipient,  
administering CO to the recipient,  
administering bilirubin to the recipient  
administering biliverdin to the recipient  
administering ferritin to the recipient,  
administering iron to the recipient,  
administering desferoxamine to the recipient,  
administering salicylaldehyde isonicotinoyl hydrazone to the recipient,  
administering iron dextran to the recipient,  
administering apoferritin to the recipient classified in classes 424/93.7,  
93,71, 93,73; 514/579, 663, 740; 600/36 and others depending, for  
example, on the treatment species of (ii).

#### SPECIES

This application also contains claims directed to the following  
patentably distinct species: as a second treatment (ii) in the donor or  
recipient or organ, tissue, cells:

inducing HO-1,  
expressing HO-1,

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inducing apoferritin,  
expressing apoferritin,  
administering HO-1,  
administering CO,  
administering bilirubin,  
administering biliverdin,  
administering ferritin,  
administering iron,  
administering desferoxamine,  
administering salicylaldehyde isonicotinoyl hydrazone,  
administering iron dextran,  
administering apoferritin.

Further, a species election of organ, tissue or cells is also required for Groups I-III.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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